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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,881	01/04/2002	Richard M. Austin JR.	4532670/6200 (KEM 42)	4794

7590 08/11/2005

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EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,881	AUSTIN, RICHARD M.	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed April 14, 2005 have been fully considered but they are not persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that that there is sufficient teaching of the source of the bacteria, i.e. any organism that respires at least partially through the skin, and states that the specification describes "the method of identification and isolation of these bacteria as to enable those skilled in the art to practice the invention as recited in claim 1."

Applicant's assertions have not been found to be persuasive. Per Bettin et al. (see Notice of References Cited enclosed), microorganisms are widespread on inner

and outer surfaces of animals; at least some of them are thought to belong to an indigenous population while others are only temporary inhabitants derived from the environment. Applicant claims any and all extracts from bacteria isolated from the skin of amphibians and (as Applicant states in the response) "certain fish, and the like" that inhibit the growth of bacteria, fungi, viruses or tumors. However, Applicant has provided no identification of the bacteria in such a manner that these bacteria can be identified by those who would practice the invention. Applicant has not identified them or provided a repeatable source. Since various amphibians, even within a given order and genus, live in different environments, each amphibian would be expected to have different bacteria found on its skin. Applicant's dissertation supports this conclusion. One who would practice Applicant's invention would be unable to determine which amphibian and which bacteria to select to obtain a specific extract that has a specific inhibitory activity. Biologically active compounds in general are very specific to the cells that they inhibit. Conventional antibiotics are generally not effective against fungal or viral infections, anti-fungal medications are generally not effective against bacterial and viral infections and anti-viral medications are generally not effective against bacterial and fungal infections and one of skill in the art would not generally consider using an anti-neoplastic compound in the treatment of a bacterial infection. Applicant's own data at page 18 of the specification indicates no predictability as to which source and which extract would provide any desired activity. It is noted that the bacteria are only identified by a subjective series of numbers, which contain no information as to the source of the bacteria or any identifying characteristic of the bacteria. While Applicant "vigorously

disputes that [taxonomic characterization or DNA-DNA hybridization and rRNA analyses] is required in order to support the present claims of the application", Applicant merely asserts that the provided information is sufficient. Applicant cites Atlas in stating that screening for the present of bacterial isolates for potential sources of antimicrobial compounds "is the norm in pharmaceutical laboratories across the world." Atlas states "The classic approach to find new antibiotic-producing strains of bacteria has been to screen large number of isolates from soil samples for microorganisms that naturally produce antimicrobial substances." Applicant admits that the inventions of claims 1-8 and 13-19 are broader than the specific bacteria identified in the application. It is submitted that Applicant's reliance on Atlas is misplace as Atlas is describing the procedure for discovery of new compounds, i.e. an inventive process. It is clear from the use of the term "potential" and "find", there is no reasonable expectation of success at the beginning of any given screening process. Per University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CAFC 2004), the written description requirement requires that "the patent specification set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed to recognize that the inventor invented what is claimed." With the limited disclosure of the specification, one who would practice the invention could not ascertain whether or not he/she had obtained any of the bacteria or extracts identified in the specification or that any extract obtained would have any given specific anti-microbial or anti-tumor activity. The practitioner would need to engage in a trial-and-error procedure that requires undue experimentation and provides no reasonable expectation of success.

As discussed in the previous office action, the scope of this claim includes individual compounds and combinations of compounds. Applicant has provided no disclosure of any compounds in the specification. Compounds are conventionally identified by their structure by those of skill in the art. See Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) ("it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it"). Applicant only identifies the bacterial extracts by their function. While a correlation of function to structure can generally be made, multitudinous different structurally disparate compounds may share the same function such that a correlation of structure to a given function may not reasonable be made. An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. Again, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004), found that the disputed patent did "not disclose any compounds that can be used in its claimed methods" and that "[w]ithout such disclosure, the claimed methods cannot be said to have been described."). Similarly, while Applicant describes an assay for screening compounds to identify those that inhibit bacteria, fungi, viruses or tumor, no such compounds are disclosed. As a result, if there is an inadequate written description of the bacteria and the extracts, there must concomitantly be an inadequate written description of the pharmaceutical compositions and methods of therapeutic use.

3. Claims 1-19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As discussed in the previous office action, there is no disclosure of any specific bacteria that may be obtained in order to produce any extract of said bacteria. While the specification suggests that any bacteria obtained from the skin of an amphibian that inhibits bacteria, fungi, viruses or tumors may be used, Applicant shows that of the 417 bacterial isolates obtained from the skin of various amphibians, only thirteen revealed the ability of inhibiting the growth of one or more of the human pathogenic species tested. This would require that one who would practice the invention engage in an undue amount of trial-and-error testing in order to identify a bacteria from the skin of amphibians and a 3% probability of finding a bacteria to fulfill the requirements of the claims is clearly not a reasonable expectation of success, absent the use of the isolates discussed by Applicant. Applicant disagrees that this 3% success rate indicates unpredictability; however, Applicant merely asserts that a 3% success rate is extremely high given the likelihood of finding isolates in other sources, such as soil where the success rate is 1 in 400,000 but provides no sources supporting for this statement. A "trial-and-error" procedure is not consistent with the statute's requirement for predictability in the disclosure for purposes of enablement. See Rochester, id. stating "In evaluating the parties' motions, the district court found that, although all of the claims

require the use of a "non-steroidal compound that selectively inhibits activity of the PGHS-2 gene," the '850 patent neither discloses any such compound nor provides any suggestion as to how such a compound could be made or otherwise obtained other than by trial-and-error research." The district court used this fact to determine that the claims were not enabled.

While Applicant state that they are prepared to make a deposit, such a statement is insufficient to overcome the rejection.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

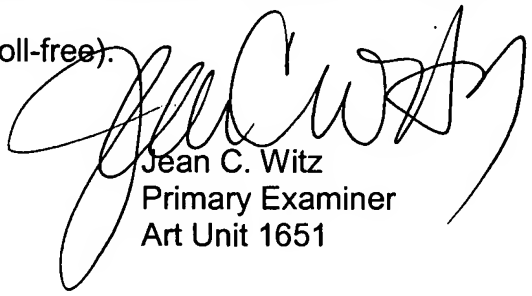
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean C. Witz
Primary Examiner
Art Unit 1651